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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,665	08/07/2003	Hiraku Murayama	029650-144	8895
21839 7590 01/10/2008 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER HOEKSTRA, JEFFREY GERBEN	
			ART UNIT 3736	PAPER NUMBER
			NOTIFICATION DATE 01/10/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/635,665

Applicant(s)

MURAYAMA ET AL.

Examiner

Jeffrey G. Hoekstra

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 12-21 and 23-35 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12-21 and 23-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/2007 has been entered.

Notice of Amendment

2. In response to the amendment filed on 10/24/2007, amended claim(s) 1, 24, and 28, canceled claim(s) 7-11, withdrawn claim(s) 4-6, and new claims 29-35 is/are acknowledged. The previous rejections of claims 1-3, 12-21, and 23-28 are withdrawn. The following new and reiterated grounds of rejection are set forth:

Claim Objections

3. Claims 1, 24, and 28 are objected to because of the following informalities: the positive recitation of "the distal side" in line 2 should apparently read "a distal side".

Appropriate correction is required.

4. Claims 1, 24, and 28 are objected to because of the following informalities: the positive recitation of "the proximal side" in lines 8, 8, and 6, respectively, should apparently read "a proximal side". Appropriate correction is required.

5. Claims 2 and 12 are objected to because of the following informalities: the positive recitation of "the material" in lines 4 and 5, respectively, should apparently read "a material". Appropriate correction is required.
6. Claim 3 is objected to because of the following informalities: the positive recitation of "the direction" in line 2 should apparently read "a direction". Appropriate correction is required.
7. Claims 20 and 21 are objected to because of the following informalities: the positive recitation of "a welded portion" in line 2 should apparently read "the welded portion". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
9. Claims 29 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a first wire not being a coil, does not reasonably provide enablement for the first wire being the distal-most portion of the guide wire. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to --use-- the invention commensurate in scope with these claims. Both Figures 1 and 6 and the Specification show and disclose the guide wire of the present invention and the distal-most portion of the guide wire is not the first wire (2) but conversely the fixing material (12).

Claim Rejections - 35 USC § 102

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 1-3, 12, 16-18, 23, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Uchino et al (US 6,001,068, hereinafter Uchino).

12. Uchino discloses a guidewire, comprising:

- a distally disposed reshapeable and non-superelastic metallic first wire (112,66,81) (the gold or platinum positively recited in column 6 lines 15-19, column 12 lines 29-33, column 15 lines 36-42) having a proximal end (the right end as best seen in Figures 1 and 9-19) inherently capable of being plastically deformed to maintain a desired shape;
- an intermediately disposed pseudo-elastic alloy second wire (A,61) (column 3 line 46 – column 4 line 6) having a smaller elastic modulus than the first wire and a distal end (the left end as best seen in Figures 1 and 9-19); and
- a proximally disposed third wire (B,62) (column 4 lines 7-25) having a larger elastic modulus than the second wire (the stainless steel for example positively recited in column 4 lines 7-25);
- wherein said first and second wires have a common longitudinal axis, are coaxial, and are welded at a welded portion at the distal and proximal ends by spot or butt-resistance welding (column 7 lines 19-67 and column 8 lines 16-22) (as best seen in Figure 12) of the end faces of the two wires in a nearly perpendicular orientation with respect to the longitudinal axis,

- wherein the second and third wire are joined to each other by spot or butt-resistance welding (column 7 lines 19-67 and column 8 lines 16-22) (as best seen in Figures 1-4, 9-15, and 17-19), and
- wherein the guidewire has a taper extending from the proximal end to the distal end (as best seen in Figures 9, 14, and 17).

Claim Rejections - 35 USC § 103

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino et al. Uchino et al discloses the claimed invention but does not disclose expressly the first wire ranging in length from 10 to 1,000 mm. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the first wire of the guidewire as taught by Uchino et al with the claimed length range, because Applicant has not disclosed that disclosed length provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the distal most wire as taught by Uchino et al, because it configures the distal region of a guidewire for navigating tortuous vasculature and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Uchino et al. Therefore, it would have been an obvious matter of design choice to modify Uchino et al to obtain the invention as specified in the claim(s).

15. Claims 19-21, 24-27, 30, and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino in view of Palermo et al (US 5,769,796, hereinafter Palermo). Uchino discloses the claimed guidewire, as set forth above, except for expressly disclosing configuring the guidewire with a spiral coil covering at least the distal end portion of the first wire, wherein the welded portion between first and second wires is located distal or proximal the proximal end of the spiral coil, wherein the coil covers the welded portion and is spaced outwardly away from the welded portion, wherein at least a portion of the spiral coil is located distally beyond a distal end of the welded portion, wherein the spiral coil possess an axial extent greater than an axial extent of welded portion, wherein the spiral coil is fixed at an intermediate portion to the first wire with a first fixing material, and wherein a second fixing material fixes the distal end portion of the spiral coil to the first wire. Palermo teaches configuring a guidewire (100) with a spiral coil of wire (112) covering at least the distal end portion of a first wire (126), wherein a welded portion (128) between the first (126) and a second wire (122) is located distal or proximal the proximal end of the spiral coil (as best seen in Figures 5A and 5B), wherein the coil covers the welded portion and is spaced outwardly away from the welded portion (as best seen in Figures 5A and 5B), wherein at least a portion of the spiral coil is located distally beyond a distal end of the welded portion (as best seen in Figures 5A and 5B), wherein the spiral coil possess an axial extent greater than an axial extent of welded portion (as best seen in Figures 5A and 5B), wherein the spiral coil is fixed at an intermediate portion to the first wire with a first fixing material (128), and wherein a second fixing material (110) fixes the distal end portion of the spiral coil to the

first wire. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Uchino and Palermo. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Uchino with the components as taught by Palermo to achieve the predictable results of configuring the mechanical properties (i.e. flexibility, elastic modulus, etc...) of a guidewire for navigating tortuous vasculature.

Response to Arguments

16. Applicant's arguments with respect to claims 1-3, 12-21, and 23-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736

A handwritten signature in black ink, appearing to read "M. Hoekstra", is located in the lower right quadrant of the page.